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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,357	03/25/2004	John E. Uschold	12013/50601	5454
23838	7590	11/16/2007		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER DESANTO, MATTHEW F	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/808,357

Applicant(s)

USCHOLD, JOHN E.

Examiner

Matthew F. DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, 13, 15-18, 20-23 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 13, 15-18, 20-23 and 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no teaching of a distal end with first and second extensions that are non-pointed, therefore this subject matter drawn to figures 3-6.

3. The 112 2<sup>nd</sup> Paragraph Rejection has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 6-10, 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Magasi (USPN 4,826,492).

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Magasi discloses a needle (1) comprising a shaft having a distal end defining a distal opening (20, 22) and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft, wherein the distal most end is a curvilinear distal tip, wherein the distal end comprises opposing first and second surfaces and the first surface (24) is indented towards the second surface; wherein the distal end comprises opposing first and second extensions, which are angled towards each other and the second extension is longer than the first in a direction parallel to the longitudinal axis of the shaft and these extensions and mutually define at least one opening offset from the longitudinal axis of the shaft (see figure 6 and entire reference).

Claims 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Dye (USPN 3,788,320).

Dye discloses a needle (20) comprising a shaft having a distal end defining a distal opening (40,42) and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft, wherein the distal most end is a curvilinear distal tip, wherein the distal end comprises opposing first and second surfaces and the first surface (62) is indented towards the second surface; wherein the distal end comprises opposing first and second extensions, which are angled towards each other and the second extension is longer than the first in a direction parallel to the longitudinal axis of the shaft and these extensions and mutually define at least one opening offset from the longitudinal axis of the shaft (see figure 3-8 and entire reference).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magasi in view of Alchas U.S. Patent Number 4,537,593.

Magasi discloses the device as described above in reference to claim 1, but fails to explicitly disclose a port or that the distal end of the needle is tapered.

Alchas ('593) describes that the distal end of the shaft 26 comprises at least one port (36) on it's side, the distal end terminates in a curvilinear distal tip (31) and the distal end of the shaft (26) is tapered, and the needle (20) being on the distal end of a syringe (117) see figures 1, 2 and 14.

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It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Magasi by incorporating the port and tapered shaft of the type taught by Alchas, in order to vent air and allow access to narrow target areas.

Claims 11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Altman U.S. Patent Number 6,346,099.

Magasi discloses the device as described above in reference to claim 1, but fails to explicitly disclose a catheter and syringe attached to the needle, nor a method of using the needle to deliver a therapeutic agent.

Altman discloses a similar device and method of use. Altman ('099) discloses that the needle (312) is on the distal portion of a catheter (5). Moreover Altman ('099) teaches a method of delivering a therapeutic agent to a target site of a body comprising providing a drug delivery device (306) containing a therapeutic agent and comprising a needle (312) at a distal portion thereof; and delivering the therapeutic agent through the needle to a target site of a body (col. 3 line 18), wherein the drug delivery device is a catheter (5), the target site is the heart (col. 3 line 29), the method comprising of directly delivering the therapeutic agent to the target site (col. 3 line 22).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Magasi by incorporating the method of the type taught by Altman in order to deliver drugs to the heart.

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Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magasi in view of Luther et al U.S. Patent Number 5,873,864.

Magasi discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of placing the needle in an access port.

Luther et al discloses a similar device and a method including inserting the needle of the drug delivery device (10) into a drug delivery port (32) to access the drug delivery port, and wherein accessing the drug delivery port (32) comprising introducing a therapeutic agent through the needle (12) into the drug delivery port (32) comprising a septum (68) and the needle pierces (12) the septum (68) to access the port, and wherein the drug delivery device is a catheter (30), (col. 4 line 23. and figures 1-4).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Magasi by incorporating the method of the type taught by Luther et al in order to allow a sealed, safe manner in which to administer a therapeutic agent.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magasi in view of Gross U.S. Patent Number 5,843,048. Magasi discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of delivery of a therapeutic agent to a spinal column.

Gross discloses a similar device and a method including; a method of delivering a therapeutic agent to a spinal column comprising: providing a drug delivery device (22) containing a therapeutic agent and comprising the needle at a distal portion thereof; and introducing the therapeutic agent through the needle into a spinal column (col. 7 line 2).

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It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Magasi by incorporating the method of the type taught by Gross et al in order to allow delivery to the spinal cord without additional coring.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magasi in view of Johnson U.S. Patent Number 5,817,052.

Magasi discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of collecting a fluid sample creating a vacuum.

Johnson discloses and a method including; a method of collecting a fluid sample from a body comprising: providing a drug delivery device comprising the needle at a distal portion thereof, inserting the needle into a fluid containment site of a body; and creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body, (col. 19 line 40) and the fluid sample consists of blood, (col. 19 line 7).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Magasi by incorporating the method of the type taught by Johnson in order to safely withdraw fluids.

### ***Response to Arguments***

Applicant's arguments filed on September 5, 2007 have been fully considered but are not persuasive.

With regards to the 112 1<sup>st</sup> paragraph the examiner is not convinced with the arguments because the specification doesn't disclose the specific embodiment and there is no suggestion of making the embodiment shown in figure 3-6 with blunt tips. There is also no criticality for doing this as well. The specification does state that different aspects of the invention can be used, but



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there needs to be some suggestion or criticality provided in the specification to want to make the specific embodiment or some teaching. The specification fails to do this, thus the examiner maintains the 112 1<sup>st</sup> paragraph.

With regards to Magasi the examiner is not convinced with the arguments. The examiner spoke with applicant's representative and discussed how the examiner was interpreting the prior art and why the prior art would read on the claimed invention. Even though the finished product of the prior art is different then the claimed invention, during the process of making the finished process, the prior art would make the claimed invention and thus have all the claimed elements. In the prior art the catheter is being interpreted as the proximal portion and the lumen in the prior art allows drugs to pass, and the needle, shaft and catheter are formed as a one-piece element, thus fulfilling the requirements of the claims.

With regards to Dye, the examiner also disagrees with the arguments set forth. Dye teaches that there are openings and that fluid can pass through the openings, see Column 3, line 39-43. Claims 34-38 never disclose a blunt tip and therefore the examiner is unsure about this argument.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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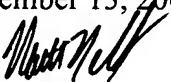
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto  
Art Unit 3763  
November 13, 2007



**MATTHEW F. DESANTO**  
PRIMARY EXAMINER